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Dated: 12/21/04 Signature: Judy Bridgwater
(Judy Bridgwater)

Docket No.: 549172000100
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Micheal L. GRUENBERG

Application No.: 08/700,565

Art Unit: 1644

Filed: July 25, 1996

Examiner: R. Schwadron

For: AUTOLOGOUS IMMUNE CELL THERAPY: CELL COMPOSITIONS, METHODS AND APPLICATIONS TO TREATMENT OF HUMAN DISEASE

PETITION TO WITHDRAW HOLDING OF ABANDONMENT

MS Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the Notice of Abandonment dated December 2, 2004. The Notice states that the application has been abandoned for failure to timely respond to the Office communication mailed May 26, 2004. Enclosed herewith are copies of the Amendment in Response to Office Communication which was mailed November 24, 2004 via Express Mail. Also enclosed is a copy of the date-stamped Express Mail Label, and a copy of the return postcard stamped received by the USPTO on November 24, 2004. Applicants hereby request withdrawal of the holding of abandonment and entry of the response then filed.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 549172000100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: December 21, 2004

Respectfully submitted,

By _____
Laurie L. Hill, Ph.D.
Registration No.: 51,804
MORRISON & FOERSTER LLP
3811 Valley Centre Drive, Suite 500
San Diego, California 92130
(858) 720-7955

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EMS

Atty Docket No.: 549172000100

Inventor: Micheal L. GRUENBERG

Application No.: 08/700,565 **Filing Date:** July 25, 1996

Title: AUTOLOGOUS IMMUNE CELL THERAPY: CELL COMPOSITIONS, METHODS AND APPLICATIONS TO TREATMENT OF HUMAN DISEASE

Documents Filed:

Transmittal (1 page)

Fee Transmittal (1 page, + duplicate)

Petition for Extension of Time Under 37 CFR 1.136(a) (1 page)

Amendment in Response to Office Communication (4 pages)

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	08/700,565
Filing Date	July 25, 1996
First Named Inventor	Micheal L. GRUENBERG
Art Unit	1644
Examiner Name	R. Schwadron
Attorney Docket Number	549172000100

Total Number of Pages in This Submission	10

ENCLOSURES (*Check all that apply*)

- [X] Fee Transmittal Form (1 pg., + dup.)
- [ ] Fee Attached
- [X] Amendment/Reply (6 pgs.)
- [ ] After Final
- [ ] Affidavits/declaration(s)
- [X] Extension of Time Request (1 pg.)
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
- [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [X] Other Enclosure(s) (please Identify below):

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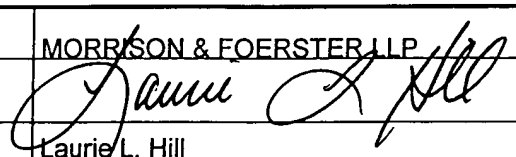
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	MORRISON & FOERSTER LLP		
Signature			
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Date	November 24, 2004	Reg. No.	51,804

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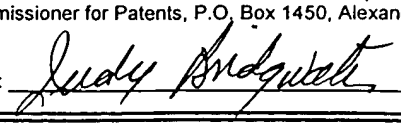
Dated: November 24, 2004 Signature:  (Judy Bridgwater)

sd-232555

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Dated: 11/24/04 Signature: Judy Bridgwater (Judy Bridgwater)

Docket No.: 549172000100 (PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Micheal L. GRUENBERG

Application No.: 08/700,565

Filed: July 25, 1996

For: AUTOLOGOUS IMMUNE CELL THERAPY: CELL COMPOSITIONS, METHODS AND APPLICATIONS TO TREATMENT OF HUMAN DISEASE

Examiner: R. Schwadron

Art Unit: 1644

AMENDMENT IN RESPONSE TO OFFICE COMMUNICATION

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the Office Communication dated May 26, 2004, for which a response was due on June 26, 2004. Filed herewith is a Petition and fee for a five-month extension of time, thereby extending the deadline for response to November 26, 2004. Accordingly, this response is timely filed. Reconsideration and allowance of the pending claims, as amended, are respectfully requested.

AMENDMENTS TO THE CLAIMS

Claims 1-21 (Canceled)

Claim 22 (Currently amended): A method for generating clinically relevant cell numbers of Thl cells, comprising:

(a) collecting material containing mononuclear T lymphoid cells from a mammal;

(b) activating the T lymphoid cells to alter their cytokine production profile by causing differentiation of the cells into Thl cell, wherein the cells are activated in the presence of either or both interferon-γ and IL-2 or anti-IL-4 antibody or αB7.2 mAb or TGF-β, whereby cells differentiate into Th1 cells; and

(c) in the absence of exogenous IL-2 ~~H-2~~, inducing cell proliferation and expanding the cells under conditions that produce at least about 10^{10} cells/liter of a homogeneous population of Th1 cells, wherein:

a homogeneous population of Th1 cells comprises greater than about 50% Th1 cells; and

the resulting cells do not require co-infusion of IL-2 for activity.

Claim 23 (Previously presented): The method of claim 22, wherein the Th1 cells with altered cytokine profile are purified.

Claim 24 (Previously Presented): The method of claim 22, wherein the Th1 cells with altered cytokine profile are specific for a defined antigen.

Claim 25 (Previously Presented): The method of claim 23, wherein the Th1 cells with altered cytokine profile are specific for a defined antigen.

Claims 26-28 (Canceled)

Claim 29 (Currently amended): The method of claim [[~~28~~ 22]], wherein anti-IL-4 monoclonal antibodies are also present during activation.

Claim 30 (Canceled)

Claim 31 (Previously Presented): The method of claim 22, wherein the cells are expanded in the presence of two or more monoclonal antibodies.

Claim 32 (Previously Presented): The method of claim 31, wherein the monoclonal antibodies are specific for CD3 or CD2, combined with any combination of monoclonal antibodies specific for one or more of the following: CD4, CD8, CD11a, CD27, CD28, CD44 and CD45RO.

Claim 33 (Original): The method of claim 22, wherein the cells are expanded in a hollow fiber bioreactor.

Claims 34-154 (Canceled)

Claim 155 (Currently amended): A method for generating clinically relevant numbers of Th1 cells for autologous cell therapy, comprising:

(a) collecting material comprising body fluid or tissue containing mononuclear cells from a mammal;

(b) treating the cells to induce differentiation of mononuclear cells into Th1 cells, wherein the cells are treated with either or both interferon-γ and IL-2, or anti-IL-4 antibody or αB7.2 mAb or TGF-β to induce differentiation of Th1 cells; and

(c) contacting the resulting differentiated cells with two or more different activating proteins specific for cell surface proteins present on the cells in an amount sufficient to induce *ex vivo* cell expansion, whereby clinically relevant numbers of cells for autologous cell therapy are generated, wherein the contacting is effected in the absence of exogenous ~~cytokines~~ [[IL-2]].

Claim 156 (Previously Presented): The method of claim 155, wherein cells are purified from the material.

Claim 157 (Currently amended): The method of claim 155, wherein the treating ~~and contacting steps~~ step occurs in the absence of exogenous cytokines.

Claim 158 (Previously Presented): The method of claim 155, wherein the cells are specific for a selected antigen.

Claims 159-164 (Canceled)

Claim 165 (Previously Presented): The method of claim 155, wherein the proteins specific for cell surface proteins are one or more monoclonal antibodies specific for immune cell surface proteins.

Claim 166 (Previously Presented): The method of claim 165, wherein the monoclonal antibodies are specific for CD3 or CD2, combined with any combination of monoclonal antibodies specific for one or more antigens selected from the group consisting of CD4, CD8, CD11a, CD27, CD28, CD44 and CD45RO.

Claim 167 (Previously Presented): The method of claim 155, wherein cell expansion is effected in a hollow fiber bioreactor.

Claim 168 (Previously Presented): The method of claim 155, wherein the cells are expanded to about 10^9 cells or greater.

Claim 169 (Canceled)

Claim 170 (Currently amended): The method of claim 155, wherein the expanded cells are predominantly Th1~~, Th2, Th3~~ cells.

Claim 171 (Previously Presented): The method of claims 155, wherein the expanded cells are contained in a volume of one liter or less.

Claim 172 (Previously Presented): The method of claim 155, wherein the expanded cells are contained in a volume of about 500 mls or less.

Claims 173-210 (Canceled)

Claim 211 (Currently amended): A method for generating immune cells for autologous cellular immunotherapy, comprising:

collecting leukocyte containing material from a mammal;

differentiating the leukocytes into Th1 cells by contacting the cells with a composition comprising interferon-γ, or anti-IL-4 antibody or αB7.2 mAb or TGF-β; and

exposing the leukocyte-containing material to two or more different mitogenic monoclonal antibodies to induce *in vitro* cell proliferation of Th1 cells sufficient for infusion into the mammal for use in an immunotherapy treatment, wherein the *in vitro* cell proliferation is produced without the use of exogenous interleukin-2.

Claim 212 (Previously Presented): The method of claim 211, wherein at least 10^{10} cells are produced.

Claim 213 (Previously Presented): The method of claim 211, wherein the cells are at a density of 1×10^8 cells/ml.

Claims 214-217 (Canceled)

REMARKS

Claims 22-25, 29, 31-33, 155-158, 165-168, 170-172 and 211-213 are pending in this application. Claims 22, 29, 155, 157, 170, and 211 are amended herewith. It is believe that no new matter is added. No claim has been allowed.

According to the Office Communication dated May 26, 2004, the amendment to the claims filed on January 30, 2003 does not comply with the requirements of 37 C.F.R. § 121(c) because the terms "by contacting the cells with" and "two or more" were added to the claim 211 without indicating that the phrases were added. Applicants submit a complete set of amended claims as they appeared in the amendment filed January 30, 2003 with the indicated phrases underlined to comply with the *current* requirement of 37 C.F.R. § 121(c). Applicants also note that minor errors in the claims as filed on January 30, 2003 are also corrected by the amendments submitted herewith.

Applicants respectfully request the substantive consideration of the claims as now pending.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 54917-20001.00. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: November 24, 2004

Respectfully submitted,

By _____
Laurie L. Hill, Ph.D.
Registration No.: 51,804
MORRISON & FOERSTER LLP
3811 Valley Centre Drive, Suite 500
San Diego, California 92130
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12-23-04

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	08/700,565
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First Named Inventor	Micheal L. GRUENBERG
Art Unit	1644
Examiner Name	R. Schwadron
Total Number of Pages in This Submission: 11	Attorney Docket Number: 549172000100

ENCLOSURES (*Check all that apply*)

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	MORRISON & FOERSTER LLP Laurie L. Hill, Ph.D. - 51,804
Signature	Laurie L. Hill
Date	December 21, 2004

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Dated: 12/21/04 Signature: Judy Bridgwater (Judy Bridgwater)

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